



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

SALES OF ANTIMICROBIAL PRODUCTS
AUTHORISED FOR USE AS
VETERINARY MEDICINES,
ANTIPROTOZOALS,
ANTIFUNGALS,
AND
COCCIDIOSTATS,
IN THE UK IN 2008

2009





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SUMMARY

This is the eleventh in a series of reports designed to provide information about the sales of veterinary antimicrobial products in the UK. The data for this report have been calculated using the methodology developed in 2002.

Summary of the main points and changes to the report (all tonnages are expressed as active ingredient (a.i) unless otherwise stated)

The main points and changes presented in this year's report are:

- Report for the first time sales of veterinary antimicrobial products in the UK from 2008.
- There is a net 3 tonne decrease in sales of veterinary antimicrobials, most of which is accounted for by the combination of a decrease in sales of trimethoprim/sulphonamides and β -lactams of 3 tonnes each and an increase in sales of macrolides of 2 tonnes.
- There is a decrease in sales of products for food-producing animals of 8 tonnes and an increase of 4 tonnes for non-food animals only.
- No sales of antimicrobial growth promoters are reported as their use and sale were banned from 1 January 2006.
- Coccidiostat data for 2006 and 2007 have been restated following identification of missing data for those years.
- Medicated feedingstuff and orally administered products have been restated following identification of mis-classified products.
- In 2008 23 Kg fewer fluoroquinolones were sold than in 2007. For cephalosporins, there was an increase of 27 Kg.
- In 2008 there was an increase in sales of products imported under the SIC/STC systems, increasing from 1,043 Kg in 2007 to 3,883 Kg in 2008.
- For the third year in a row the kilograms of antimicrobial active ingredient used per tonne of live weight of animals slaughtered for food remained constant at 0.06Kg/tonne.

Trends

Total Sales

The total sales of veterinary therapeutic antimicrobials in the UK remained relatively steady between 1998 and 2003 at around 434 tonnes per annum. During 2004 total sales of antimicrobials for therapeutic use in all animals increased by 20 tonnes to 454 tonnes, but in 2005 decreased by 8 tonnes to 446 tonnes, decreased by a further 41 tonnes in 2006 to 405 tonnes, fell by 18 tonnes in 2007 to 387 tonnes and again fell in 2008 to 384 tonnes.

The sales of veterinary therapeutic antiprotozoals in 2008 were 15 tonnes, an increase of 1 tonnes since 2007. Sales of these products are exclusively for



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food-producing animals. The sales of veterinary antifungals were 4 tonnes in 2008, again an increase of 1 tonne on the previous year.

There were no sales of veterinary antimicrobial growth promoters in 2008 following the EU ban on their use or sale from 1 January 2006.

Sales of coccidiostats in 2008 were 207 tonnes, an increase of 11 tonnes from 2007 and the same figure as in 2006. Coccidiostats are used in food-producing animals only, particularly poultry reared on deep litter systems.

Food-Producing Animals

In 2008 sales of antimicrobial products for therapeutic use in food-producing animals accounted for approximately 85% (327 tonnes) of the total annual sales of 384 tonnes which was comparable with previous years. However it is not possible to identify the proportion of the 327 tonnes which was administered to animals that did not enter the food chain (for example, cattle barred from use in food via the Older Cattle Disposal Scheme).

Approximately half of the total sales of therapeutic antimicrobials were accounted for by tetracyclines in each year from 2003 to 2008. In each of the ten reporting years between 1 and 2 tonnes of fluoroquinolones were sold (less than 1% of the total). Between 69% and 82% of therapeutic antimicrobial products for food-producing animals only were sold for use as medicated feedingstuffs, over the reporting period (2003–2008), most of which are sold for use in pig and poultry farming.

Overall the sales of therapeutic antimicrobial products for use in food-producing animals showed a decrease in 2008, from the 2007 sales. There was a decrease in sales of therapeutic antimicrobials in 2008 for some of the individual food-producing species e.g. for pigs and poultry only (decreased by 21 tonnes a.i.). A decrease in sales was seen for pig only (4 tonnes a.i.) and fish only (3 tonne a.i.). Sales of poultry only products increased by 13 tonnes in 2008 compared with previous years, due to changes to the species listed on the marketing authorisations for some products. Sales of multi-species products (excluding pig and poultry only) also increased from 2007 to 2008.

Non-Food-Producing Animals

Sales of antimicrobials for veterinary medicinal products authorised only for therapeutic use in non-food-producing animals in 2008 accounted for 10% (38 tonnes) of the total annual therapeutic sales (384 tonnes). This is the third year in a row where the antimicrobial sales for companion animal only products have increased as a proportion of the total. It is currently not possible to determine what proportion of the 19 tonnes (5%) of antimicrobials sold for therapeutic use in either food-producing or non-food-producing animals was used in companion animals.



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In 2008 there was an increase in the amount of antimicrobials sold for use in dogs only and horses only (4 tonnes each) and a decrease (4 tonnes) in sales of products for use in either a combination of companion animals or other companion animals compared with 2007. The majority (95%) of dog only antimicrobial products sold were in tablet form, whereas the horse only antimicrobial products sold were mainly for adding to feed (95%).

Context

Animal health background

In addition to the normal animal health challenges facing farming the following would have had an impact on the requirement to use antimicrobials:

- In 2008 there was a second very wet summer in the UK causing large scale flooding in many areas; and
- UK pig farming continued to suffer from the presence of diseases such as Porcine Dermatitis and Nephropathy Syndrome and Post-weaning Multi-systemic Wasting Syndrome (PDNS/PMWS), which often lead to secondary infections requiring antimicrobial treatment.

Regulatory Background

All therapeutic antimicrobial products in the UK may be dispensed only under veterinary prescription.

Numbers of Livestock in the National Herd

The following table shows the number of food-producing animals recorded each year in Defra's June Census for each of the last six reporting years. All figures are quoted in thousands of individual animals and are not adjusted for seasonality.

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---------|---------|---------|---------|---------|---------|---------|
| Cattle | 10,508 | 10,588 | 10,392 | 10,270 | 10,304 | 10,107 |
| Pigs | 5,046 | 5,159 | 4,862 | 4,933 | 4,834 | 4,714 |
| Sheep | 35,812 | 35,817 | 35,416 | 34,722 | 33,946 | 33,131 |
| Poultry | 178,800 | 181,759 | 173,909 | 173,081 | 167,667 | 166,200 |

Interpreting the figures

The figures in this report should only be regarded as indicative of overall trends in sales. There is no central record kept of the use of antimicrobials in animals in the UK. However it is reasonable to assume that there is a direct relationship between the quantities of antimicrobials sold and used in the UK. Our assessment does not include any measure of the quality or the degree of uncertainty for the figures reported.



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INTRODUCTION

Antimicrobial resistance is a serious problem in human medicine resulting in increasing concerns about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. The UK Government has made clear that it takes this problem seriously and has developed a comprehensive strategy to address it so that the effectiveness of antimicrobial products in both humans and animals can be maintained. A key element of this strategy is the collection and publication of information on the quantities of antimicrobial products sold each year for veterinary use in the UK.

The Veterinary Medicines Directorate (VMD), an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra), is responsible for the authorisation of veterinary medicines in the UK. For the past eleven years, in response to recommendations made by the Advisory Committee on the Microbiological Safety of Food (ACMSF), we have collected, collated and published figures on UK sales volumes of active antimicrobial ingredients used in products authorised as veterinary medicines, growth promoters or coccidiostats. The report has been extended over time to include antiprotozoal and antifungal products.

These reports are based on sales data provided voluntarily by the veterinary pharmaceutical companies marketing these products in the UK from 1998-2004. Data for 2005 and later were collected as a statutory requirement in accordance with the provisions of EC Directive 2001/82 (as amended), following entry into force of the Veterinary Medicine Regulations 2005 (at the time of collecting these data the Veterinary Medicines Regulations 2008 was in force). It is reasonable to assume that there is a close correlation between the reported quantities of products sold and those used in the UK in the species indicated. Since 2006 this report includes products imported by Veterinary Surgeons under Special Import Certificate (SIC) or Special Treatment Certificate (STC) arrangements.

A glossary of terms used in this report can be found at Annex 1.

Methods Used

The following paragraphs provide a brief overview of the methods used to analyse the data provided by pharmaceutical companies and to calculate the sales figures in this report.



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Collection of data

We collect data from veterinary pharmaceutical companies in the first half of each calendar year for the previous full calendar year. These data are collated and verified before they are imported into a bespoke spreadsheet for analysis.

Data from the SIC and STC imports are gathered from the VMD's in-house databases and transferred into a purpose built spreadsheet for analysis.

Categorisation of data

Additional information, drawn from regulatory data on each of these products, is included in a spreadsheet. These data include the authorised administration methods, target species and an appropriate conversion factor to calculate the proportion of active antimicrobial ingredient in each product. All of these data are rechecked before any further calculations are undertaken. Data are then analysed by chemical grouping, administration methods, target species and against livestock slaughter figures.

In this year's report we have reported sales of products indicated for use in food-producing animals only, non-food animals only and for both food-producing and non-food animals. It is hoped that this will provide a valid picture of the apportionment of sales for use of veterinary therapeutic antimicrobials in the UK.

SIC and STC data were analysed and relevant data on target species etc included in the spreadsheets. Data were checked and calculations validated in-house.

Collation and publication

The resulting figures are collated into a report format and patterns and trends of sales are identified. It is not within the remit of this report to interpret these patterns. However, where appropriate, we do include information on factors that we are aware of and might have affected sales or use of antimicrobial products during the reporting period.

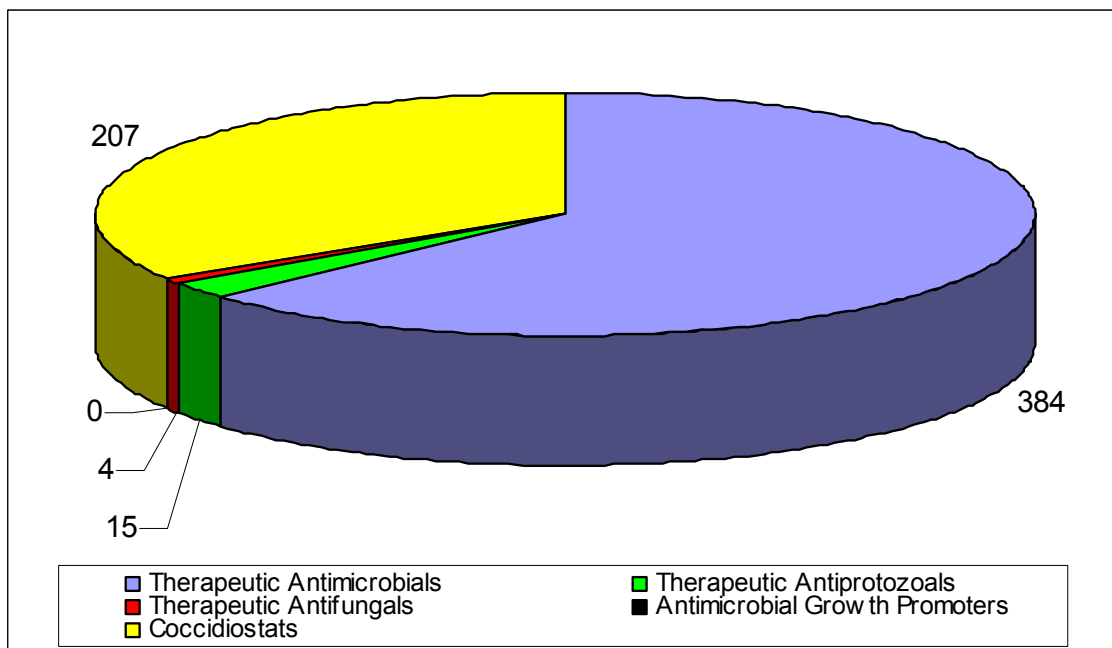
Finally, we seek comments on the draft report from the Veterinary Products Committee (VPC), the Government's independent expert advisory committee on veterinary medicines and from the Defra Antimicrobial Resistance Coordination (DARC) Group.

RESULTS

TOTAL SALES

The quantities of sales in 2008 for each of the five categories of veterinary products reported are illustrated in Figure 1. Therapeutic antimicrobials were the largest selling group (384 tonnes), followed by coccidiostats (207 tonnes), with no sales of antimicrobial growth promoters. Therapeutic antiprotozoals and antifungals were the smallest selling categories (15 tonnes and 4 tonnes respectively).

Figure 1: Quantities of therapeutic antimicrobials, antiprotozoals, antifungals and coccidiostats and antimicrobial growth promoters in tonnes a.i. sold in the UK in 2008¹



The numbers of products sold within each category of antimicrobials reported are summarised in Table 1. This is a summary of the numbers of products sold to help clarify the reported data. It is not a list of products that had marketing authorisations in 2008.

¹ Not all of the therapeutic antimicrobials are used to treat clinical disease manifested in animals. Some may be used prophylactically in whole groups of animals to prevent the establishment of disease in otherwise healthy animals, or metaphylactically to prevent spread of disease within a herd or flock. It is not possible within this report to estimate the proportion of therapeutic antimicrobials that were used to prevent or to treat diseases in animals.



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Table 1: Numbers of products sold in 2003-2008 by reporting group of products

| Group of Veterinary Product Sold | Number of Products Sold by Group 2003 | Number of Products Sold by Group 2004 | Number of Products Sold by Group 2005 | Number of Products Sold by Group 2006 | Number of Products Sold by Group 2007 | Number of Products Sold by Group 2008 |
|---|--|--|--|--|--|--|
| Therapeutic Antimicrobials comprising: | 358 | 339 | 325 | 317 | 311 | 370 |
| <i>Tetracyclines</i> | 49 | 50 | 48 | 45 | 46 | 46 |
| <i>Trimethoprim/Sulphonamides</i> | 50 | 45 | 46 | 40 | 40 | 41 |
| <i>β-lactams</i> | 124 | 120 | 113 | 120 | 110 | 131 |
| <i>Aminoglycosides</i> | 45 | 40 | 29 | 26 | 28 | 28 |
| <i>Macrolides</i> | 20 | 19 | 23 | 21 | 22 | 22 |
| <i>Fluoroquinolones</i> | 34 | 25 | 26 | 27 | 27 | 25 |
| <i>Others</i> | 36 | 40 | 40 | 38 | 39 | 41 |
| Therapeutic Antiprotozoals | 14 | 13 | 12 | 11 | 12 | 10 |
| Therapeutic Antifungals | 16 | 15 | 13 | 13 | 13 | 15 |
| Coccidiostats | 11 | 10 | 9 | 9 | 9 | 11 |

Total Sales: Therapeutic Antimicrobials

The gross quantities of antimicrobial active ingredients in therapeutic products sold between 2003 and 2008 are shown in Table 2. These sales are divided into those sold for use in food-producing animals only, non-food-producing animals only and those sold for use in a combination of both food and non-food animals. They are expressed as tonnes of base active ingredient. Table 2 also illustrates the trend in sales of these groups of products over the period 2003-2008. These figures are expressed graphically in Figure 2.

The overall sales of therapeutic antimicrobial products remained broadly the same over the period 2003-2005, varying between 435 and 454 tonnes. Since 2005 sales have been declining annually, see Table 2 and Figure 2. The fluctuations year-on-year are most likely to reflect natural changes in the incidence of disease in animals over that period. Sales in 2008 have shown a decrease of 3 tonnes to 384 tonnes. In 2008, sales of therapeutic products for use in food-producing animals only have also decreased from 335 to 327 tonnes of active ingredient, sales of therapeutic antimicrobials for use in non-



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food-producing animals have increased from 2003 to 2008 from 30 tonnes to 38 tonnes and sales of products for use in either food-producing or non-food-producing species varied between 18 and 32 tonnes showing no specific trend.

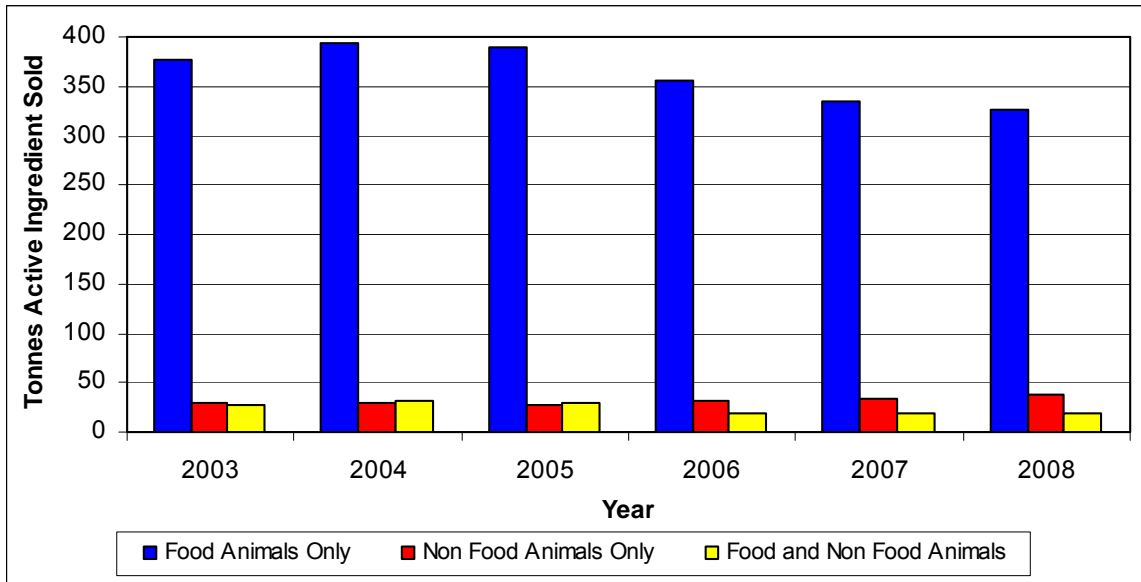
Table 2: Sales of therapeutic antimicrobials 2003–2008, in the categories of food animals only, non-food animals only and combined food and non-food animals

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---------------------------------|------------|------------|------------|------------|------------|
| | Tonnes Active Ingredient | | | | | |
| Indicated for food animals only | 377 | 393 | 390 | 356 | 335 | 327 |
| <i>Annual Actual increase/decrease</i> | (9) | 16 | (3) | (34) | (21) | (8) |
| Indicated for non-food animals only | 30 | 29 | 27 | 31 | 34 | 38 |
| <i>Annual Actual increase/decrease</i> | 6 | (1) | (2) | 4 | 3 | 4 |
| Indicated for a combination of both food and non-food animals | 28 | 32 | 29 | 18 | 19 | 19 |
| <i>Annual Actual increase/decrease</i> | (2) | 4 | (3) | (11) | 1 | - |
| Total sales of therapeutic antimicrobials | 435 | 454 | 446 | 405 | 387 | 384 |



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Figure 2: Sales of antimicrobial therapeutic products (tonnes active ingredient) 2003–2008 in food animals only, non-food animals only and in a combination of food and non-food animals



Total Sales: Therapeutic Antiprotozoals

The sales of therapeutic antiprotozoal products reported to the VMD are summarised in Table 3. Therapeutic antiprotozoals are products primarily used in the treatment and/or prevention of parasitic protozoal infections, e.g. *Eimeria* spp. Sales of therapeutic antiprotozoals showed a marked decrease in 2003 relative to 2002. Sales increased in 2004 and have remained relatively stable since then at between 12 and 15 tonnes. All antiprotozoal products authorised in the UK are for use in food-producing animal species.

Table 3: Sales of therapeutic antiprotozoals (tonnes active ingredient) in the UK 2003–2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--|---------------------------------|------|------|------|------|------|
| | Tonnes Active Ingredient | | | | | |
| Antiprotozoals | 2 | 13 | 12 | 14 | 14 | 15 |
| <i>Annual Actual Increase / Decrease</i> | (63) | 11 | (1) | 2 | (-) | 1 |



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Total Sales: Therapeutic Antifungals

The sales of therapeutic antifungal products reported to the VMD under the drug classifications imidazoles, triazoles, griseofulvin, aliphatic halogenitros and polyene macrolides are given in Table 4. Therapeutic antifungals are products primarily used to destroy or suppress the reproduction or growth of pathogenic fungi. Of the 15 sold products authorised to treat veterinary antifungal infections, 11 are indicated for use only in non-food animals. After a decrease in 2004 sales have fluctuated between 3.1 and 7.1 tonnes.

Table 4: Sales of therapeutic antifungals (tonnes active ingredient) in the UK 2003–2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--|---------------------------------|-------|------|-------|-------|------|
| | Tonnes Active Ingredient | | | | | |
| Antifungals | 13.8 | 5.1 | 7.1 | 5.2 | 3.1 | 4.1 |
| <i>Annual Actual Increase / Decrease</i> | 3.3 | (8.7) | 2 | (1.9) | (2.1) | 1 |

Total Sales: Antimicrobial Growth Promoters

The sales of antimicrobial growth promoting products from 2003-2008 are summarised in Table 5. Sales volumes have decreased from 2003 (36 tonnes) to 2006 when no sales were reported. No sales were reported since 1 January 2006 following the EU-wide ban of the sale or use of antimicrobial growth promoters.

Table 5: Sales of antimicrobial growth promoting products (tonnes active ingredient) in the UK 2003-2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--|---------------------------------|------|------|------|------|------|
| | Tonnes Active Ingredient | | | | | |
| Growth Promoting Products | 36 | 32 | 14 | 0 | 0 | 0 |
| <i>Annual Actual Increase / Decrease</i> | (6) | (4) | (18) | (14) | (0) | (0) |



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Total Sales: Coccidiostats

The sales of coccidiostats from 2003 to 2008 are shown in Table 6. Sales from 2003 have shown a generally decreasing trend. Coccidiostats are not related to any antimicrobial product currently used in human therapy. They are used exclusively in animals particularly poultry to prevent coccidiosis.

Table 6: Sales of coccidiostats (tonnes active ingredient) in the UK 2003-2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--|---------------------------------|------|------|------|------|------|
| | Tonnes Active Ingredient | | | | | |
| Coccidiostats | 240 | 224 | 231 | 207 | 196 | 207 |
| <i>Annual Actual Increase / Decrease</i> | (20) | (16) | 7 | (24) | (11) | 11 |

The sales of coccidiostats have been sub-divided into ionophore and non-ionophore compounds and are summarised in Table 7. They show that there is a decreasing trend in use of ionophore coccidiostats from 2003-2008 (79% - 73%) while sales of non-ionophore coccidiostats have been relatively stable.

Table 7: Sales of ionophore and non-ionophore coccidiostats (tonnes active ingredient) in the UK 2003–2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|----------------|---------------------------------|------------|------------|------------|------------|------------|
| | Tonnes Active Ingredient | | | | | |
| Ionophores | 190 | 173 | 173 | 151 | 144 | 150 |
| Non-ionophores | 50 | 51 | 59 | 56 | 52 | 57 |
| Total | 240 | 224 | 231 | 207 | 196 | 207 |



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IMPORTED SALES

The amounts of antimicrobial active ingredients imported into the UK via the SIC and STC systems, where no authorised products are available in the UK, are shown in Table 8. The amounts imported are relatively small and are reported in kilograms of active ingredient. Definitions of these routes of import are given in the Glossary at Annex 1.

The imports of antimicrobial active ingredients for all animals for 2004-2008 fluctuated with a marked increase in 2008. It is likely that any changes reflect the different disease issues addressed by veterinary surgeons. In each of the years 2004, 2005, 2006, 2007 and 2008 56%, 73%, 31%, 88% and 94% of those imports were for use in food-producing animals.

Table 8: Sales of imported antimicrobials (kilograms active ingredient) into the UK 2004-2008 for all animals

| | 2004 | 2005 | 2006 | 2007 | 2008 |
|---------------------------------|------------------------------------|------|------|-------|-------|
| | Kilograms Active Ingredient | | | | |
| Antimicrobial active ingredient | 159 | 252 | 189 | 1,043 | 3,883 |



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SALES BY CHEMICAL ANTIMICROBIAL GROUP

The sales of various chemical groups of antimicrobials between 2003 and 2008 are shown in Table 9 and Figure 3. These represent the main chemical groups of veterinary antimicrobials sold in the UK. Definitions of these groups can be found in the glossary at Annex 1. In all years, tetracyclines, β -lactams (including penicillin) and trimethoprim/sulphonamides accounted for the vast majority of the therapeutic antimicrobials sold. For example, in 2008, they accounted for 81% of sales, with tetracyclines accounting for 45%, β -lactams and Trimethoprim/sulphonamides 18% each. Most tetracyclines were sold for the treatment of pigs and poultry as medicated feedingstuffs (POM-VPS) under veterinary prescription.

Table 9 and Figure 3 indicate a decreasing trend for sales of sulphonamides/trimethoprim and tetracyclines whereas sales remained relatively stable for the classes of aminoglycosides and macrolides. Fluoroquinolones have shown a general increase in sales from 2003-2008. The others group has shown a gradual increase from 2004-2008.

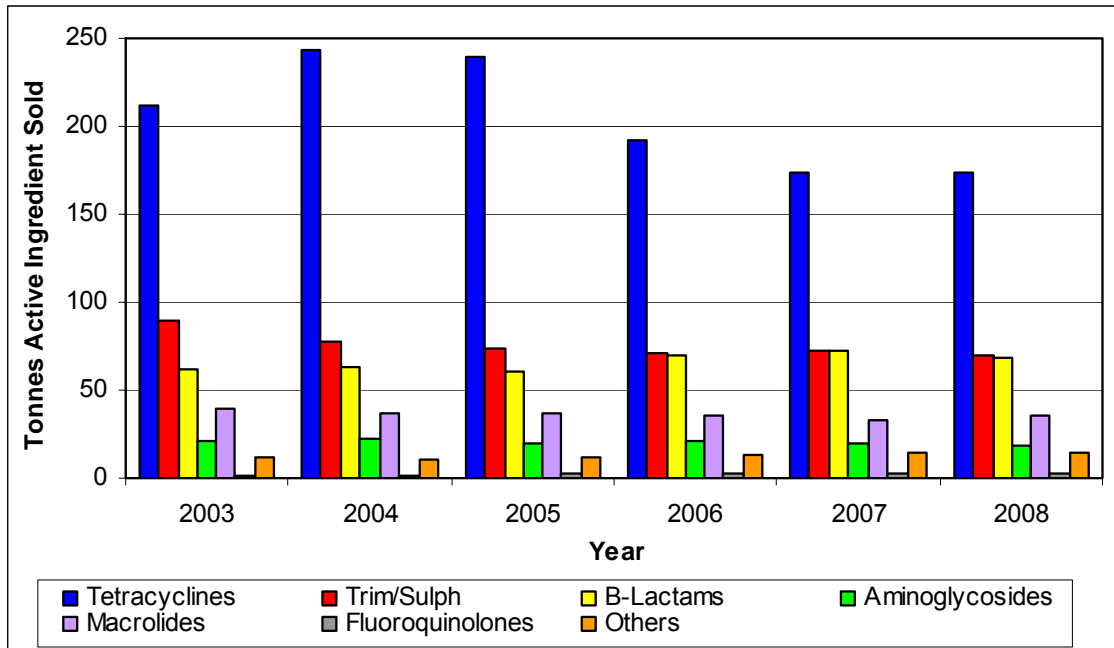
The numbers of different products sold within each of these chemical classes of products are given in Table 1.

Table 9: Sales of total antimicrobial therapeutic products by chemical grouping (tonnes active ingredient) 2003–2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--------------------------------|---------------------------------|------------|------------|------------|------------|------------|
| | Tonnes Active Ingredient | | | | | |
| Tetracyclines | 212 | 243 | 240 | 192 | 174 | 174 |
| Trimethoprim/ Sulphonamides | 89 | 77 | 74 | 71 | 73 | 70 |
| β -Lactams | 62 | 63 | 60 | 70 | 72 | 69 |
| Aminoglycosides | 21 | 22 | 20 | 21 | 20 | 18 |
| Macrolides | 39 | 37 | 37 | 36 | 33 | 35 |
| Fluoroquinolones * | 1 | 1 | 2 | 2 | 2 | 2 |
| Other | 12 | 11 | 12 | 13 | 14 | 15 |
| Total | 435 | 454 | 446 | 405 | 387 | 384 |

*fluoroquinolones (kg) 1,364 1,412 1,451 1,616 1,951 1,928

Figure 3: Sales of total antimicrobial therapeutic products (tonnes active ingredient) 2003–2008



Where it is possible within the bounds of company confidentiality, the larger classes of antimicrobials have been sub-divided, as suggested by a stakeholder, to give a more detailed picture of antimicrobial use in the UK, see Table 10.



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Table 10: Sales of antimicrobial therapeutic products by sub-chemical grouping (tonnes active ingredient) 2003–2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--|-----------|-----------|-----------|-----------|-----------|-----------|
| Trimethoprim/ Sulphonamides | 89 | 77 | 74 | 71 | 73 | 70 |
| Trimethoprim | 15 | 13 | 12 | 12 | 12 | 12 |
| Sulphonamides | 74 | 64 | 62 | 59 | 61 | 58 |
| β-Lactams | 62 | 63 | 60 | 70 | 72 | 69 |
| Cephalosporins* [#] | 3 | 3 | 4 | 6 | 6 | 6 |
| Penicillins** | 16 | 14 | 12 | 13 | 15 | 13 |
| Other Penicillins*** | 43 | 46 | 44 | 51 | 51 | 50 |
| Aminoglycosides | 21 | 22 | 20 | 21 | 20 | 18 |
| Streptomycins | 7 | 6 | 6 | 6 | 7 | 6 |
| Neomycin and Framycetin | 5 | 6 | 5 | 5 | 2 | 1 |
| Others**** | 9 | 11 | 9 | 10 | 11 | 11 |

cephalosporins (kg) 3,037 3,240 3,969 5,639 6,215 6,242

* = all generations of cephalosporins are included in this group.

** = includes potassium penicillin, benzyl penicillin, procain penicillin.

*** = includes cloxacillin, amoxycillin, ampicillin, nafcillin, penthamate hydroide.

**** = includes gentamicin, apramycin, kanamycin, spectinomycin.



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SALES BY ROUTE OF ADMINISTRATION

General

The major routes of administration of antimicrobials sold in 2003–2008 are listed in Table 11 and Figure 4. In 2008 medicated feedingstuffs made up 59% of the total therapeutic antimicrobials sold, whilst oral/water and injectable products accounted for 29% and 10% respectively. Intramammary products and other therapeutic antimicrobial products (creams, aerosols, drops, etc) contributed 1% and 0.5% respectively.

Table 11: Sales of total therapeutic antimicrobials (tonnes active ingredient) by route of administration 2003–2008

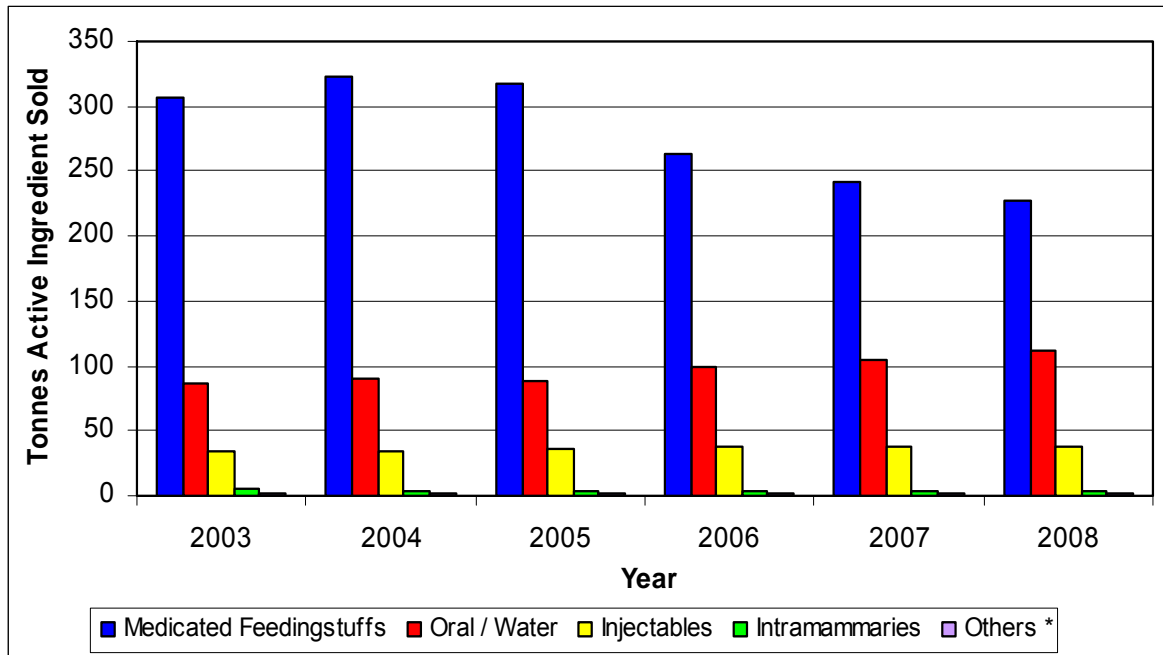
| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--------------------------|---------------------------------|------------|------------|------------|------------|------------|
| | Tonnes Active Ingredient | | | | | |
| Medicated Feedingstuffs* | 307 | 323 | 317 | 264 | 241 | 228 |
| Oral/Water* | 87 | 91 | 88 | 99 | 104 | 112 |
| Injectables | 34 | 34 | 36 | 37 | 37 | 38 |
| Intramammaries | 5 | 4 | 3 | 3 | 3 | 4 |
| Others | 2 | 2 | 2 | 2 | 2 | 2 |
| Total | 435 | 454 | 446 | 405 | 387 | 384 |

*These numbers have been restated following identification of mis-classified products.



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Figure 4: Sales of total therapeutic antimicrobials (tonnes active ingredient) by route of administration 2003–2008



* others includes aerosols, creams, ear and eye medications.

Intramammary Products

Sales of intramammary products vary between 3,125 and 4,735 kilograms active ingredient across the period 2003-2008 (see Table 12). Sales of lactating cow products increased to 1,775 kilograms in 2008 and sales of dry cow therapy products increased to 2,317 kilograms.

Table 12: Sales of antimicrobial intramammary products (kilograms active ingredient) 2003–2008²

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|------------------------|------------------------------------|--------------|--------------|--------------|--------------|--------------|
| | Kilograms Active Ingredient | | | | | |
| Dry Cow Products | 2,590 | 1,979 | 1,750 | 2,002 | 1,880 | 2,317 |
| Lactating Cow Products | 2,145 | 1,886 | 1,375 | 1,266 | 1,383 | 1,775 |
| Total | 4,735 | 3,865 | 3,125 | 3,268 | 3,263 | 4,092 |

² Sales of intramammary products are reported in kilograms.



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SALES BY ANIMAL SPECIES

Food Animal Species

The breakdown of the sales of antimicrobials indicated for use in food animal species only is shown in Table 13 and Figure 5. Table 13 shows that in 2008 59% of antimicrobial products sold for food animals only were authorised for use in a combination of pigs and poultry only. Between 5 and 9% of total antimicrobials sold for use in food-producing animals were for use in more than one food producing species (excluding those for pig and poultry only) in any year between 2003 and 2008. The largest percentage of single species products is sold for use in pigs and these sales contributed 19% in 2008 of the total sales of products for food-producing animals only. Multi-species products are authorised for use in more than one food-producing animal only. This group does not include 'pig and poultry only' products.

Table 13: Sales of total therapeutic antimicrobials for food-producing animals only (tonnes active ingredient) by food animal species 2003–2008

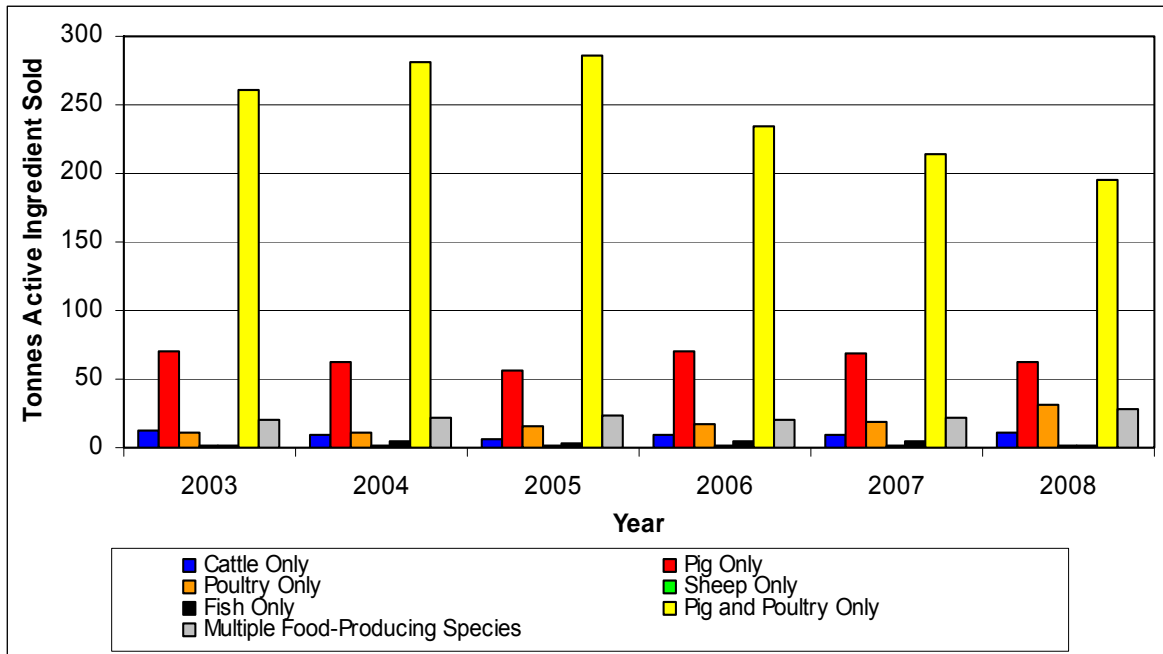
| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---------------------------------|------------|------------|------------|------------|------------|
| | Tonnes Active Ingredient | | | | | |
| Cattle Only Products | 12 | 10 | 7 | 10 | 9 | 11 |
| Pig Only Products | 70 | 63 | 56 | 71 | 66 | 62 |
| Poultry Only Products | 11 | 11 | 15 | 17 | 18 | 31 |
| Sheep Only Products | <1 | <1 | <1 | <1 | <1 | <1 |
| Fish Only Products | 2 | 4 | 3 | 4 | 4 | 1 |
| Pig and Poultry Combined Only | 261 | 282 | 286 | 234 | 216 | 195 |
| Multi Species Products In Food Animals Only | 21 | 22 | 23 | 21 | 22 | 28 |
| Total | 377 | 393 | 390 | 358 | 335 | 327 |

This year for the second time we have analysed sales for the category of pig and poultry only products based on estimates of use provided by the pharmaceutical companies with the marketing authorisations for the products. It is estimated in 2008 that 60% of the 195 tonnes sold for use were used in pigs, and 38% were used in poultry. Approximately 2% were sold for off-label use in bird species other than those for which the products are authorised for e.g. duck, turkey, game.



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Figure 5: Total sales of therapeutic antimicrobials (tonnes active ingredient) for food-producing animals only 2003–2008



Non-Food Animal Species

Table 14 shows the sales of antimicrobials indicated for use in different species of non-food animals only. In 2008, 64% of all antimicrobials authorised for use in non-food-producing animals were sold only for use in non-food-producing horses only and 30% in dogs only. These figures are similar for other reporting years.

Table 14: Sales of total therapeutic antimicrobials for non-food-producing animals only (kilograms active ingredient) by animal species 2003-2008³

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|------------------------------------|---------------|---------------|---------------|---------------|---------------|
| | Kilograms Active Ingredient | | | | | |
| Dog Only Products | 4,649 | 4,976 | 5,715 | 7,764 | 7,249 | 11,533 |
| Horse Only Products | 14,414 | 14,041 | 15,629 | 17,010 | 19,975 | 24,139 |
| Other Products For Use In Non-food Animals Only | 10,661 | 10,397 | 5,122 | 5,660 | 6,397 | 2,243 |
| Total | 29,725 | 29,417 | 26,466 | 30,435 | 33,621 | 37,915 |

³ Sales of therapeutic antimicrobials for non-food-producing animals only are reported in kilograms.



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ANTIMICROBIAL SALES AND LIVESTOCK REARED

The live weights of animals slaughtered for food in the UK from 2003-2008 are shown in Table 15 and Figure 6. The Defra Statistics Division provided the data for livestock. The Centre for Environment, Fisheries and Aquaculture Science (CEFAS) provided the UK fish production data and the Scottish Government and the Department of Agriculture and Rural Development in (DARD) provided the fish production data, for Scotland and Northern Ireland respectively.

The total live weight of animals slaughtered for food generally increased between 2003 and 2007, but slightly fell again in 2008 whilst total sales of therapeutic antimicrobials and antimicrobial growth promoters for food animals decreased (Table 16). Cattle and poultry production decreased in 2008 compared with 2007, while pig and fish production increased slightly.

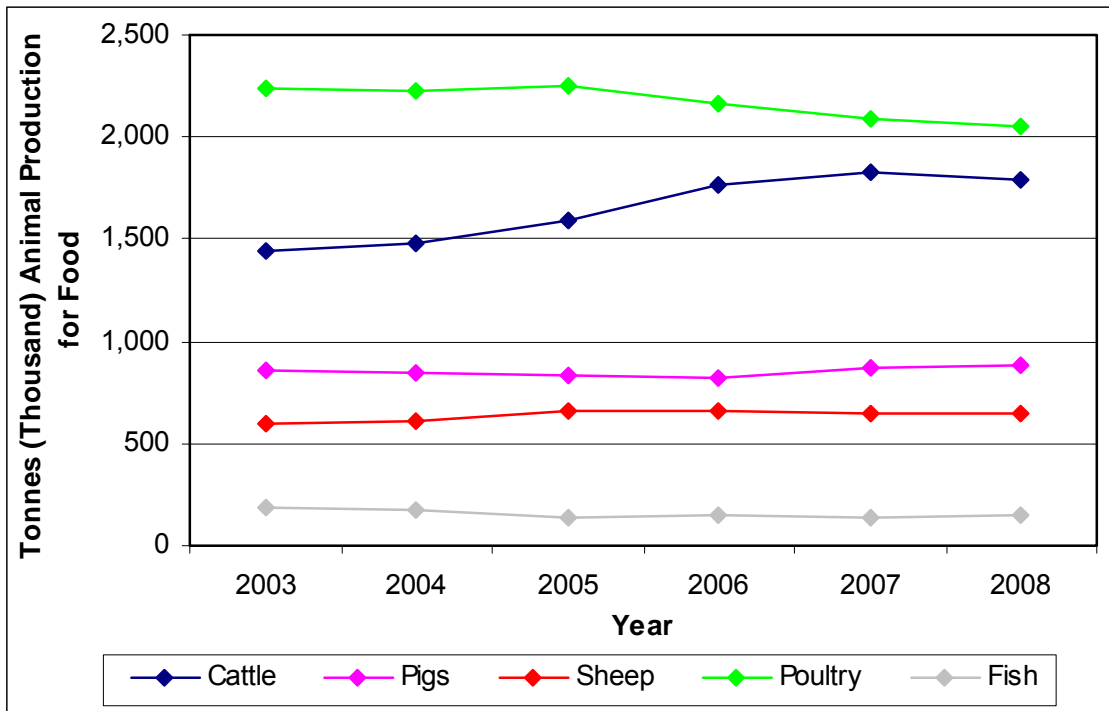
Table 15: Live weight ('000 tonnes) of animals slaughtered for food use 2003–2008

| | 2003 | 2004* | 2005 | 2006 | 2007 | 2008 |
|--------------|---|--------------|--------------|--------------|--------------|--------------|
| | '000 Tonnes live weight animals slaughtered for food | | | | | |
| Cattle | 1,449 | 1,477 | 1,586 | 1,762** | 1,831** | 1,786** |
| Pigs | 859 | 843 | 833 | 825 | 875 | 882 |
| Sheep | 598 | 609 | 658 | 655 | 646 | 649 |
| Poultry | 2,238 | 2,226 | 2,252 | 2,159 | 2,085 | 2,048 |
| Fish | 183 | 170 | 140 | 144 | 143 | 151 |
| Total | 5,327 | 5,325 | 5,469 | 5,545 | 5,580 | 5,516 |

* 2004 was a 53 week reporting year. The data for cattle, pigs, and sheep have been normalised by Defra Statistics Branch to a 52 week reporting year to allow direct comparison with data from other years.

** The OTMS rule ceased on 22 January 2006 when the OCDS scheme replaced it.

Figure 6: Live weight ('000 tonnes) of animals slaughtered for food use 2003–2008



Many farm animals are reared to slaughter without the use of therapeutic antimicrobials. Other animals such as dairy cows may be treated with antimicrobials but are not slaughtered for food use because of the older cattle disposal scheme (OCDS) and, before 22 January 2006, the over 30 months scheme (OTMS). However, if it was assumed that total antimicrobials sold for food-producing animals only were used solely in animals slaughtered for food, 1 tonne of antimicrobial would have been used in the production of 12,898, 12,529, 13,537, 15,576, 16,657 and 16,869 tonnes of live weight of animals slaughtered in the years 2003-2008 (see Table 16). Using the same assumptions, between 60 and 80g of antimicrobial was sold for each tonne of live weight animal slaughtered.

The figures for live weight of animals slaughtered are only those animals fed and slaughtered within the UK and no account has been taken of those live animals exported. Furthermore, the live weight slaughter figures do not include animals slaughtered via the OCDS and OTMS or selective culls (e.g. FMD, swine fever-infected animals), i.e. animals slaughtered but not used in food production. The numbers of cattle slaughtered annually under OTMS over the reporting period 2003–2005 are 752,914, 801,748 and 706,787 respectively. In 2006 50,400 cattle were culled via the OTMS and 150,411 by the OCDS (total culled 200,811). In 2007 127,559 and in 2008 128,345 cattle were culled via the OCDS.



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Some animals that receive therapeutic antimicrobials may not enter the food chain for a number of other reasons. Therefore, a proportion of the food-producing animals that have been treated with antimicrobials do not ultimately end up as human food. It is not possible to take these factors into account in preparing this report so our figures are likely to be an over-estimate. If they were taken into account, the quantity of antimicrobials used to produce each tonne of animal slaughtered for human food would be considerably less.

Table 16: Total live weight ('000 tonnes) of animals slaughtered for food use (data sources see above) against total antimicrobial product sales for food-producing animals only (tonnes active ingredient) 2003-2008

| | 2003 | 2004 | 2005 | 2006* | 2007* | 2008* |
|--|--------|--------|--------|--------|--------|--------|
| Total live weight animals slaughtered for food use ('000 tonnes) | 5,327 | 5,325 | 5,469 | 5,545 | 5,580 | 5,516 |
| Total antimicrobials (therapeutic and growth promoters) (tonnes) sold for food animals (tonnes a.i.) | 413 | 425 | 404 | 356 | 335 | 327 |
| Live weight of animals slaughtered (tonnes) for food per tonne of antimicrobial a.i. sold | 12,898 | 12,529 | 13,537 | 15,576 | 16,657 | 16,869 |
| Kg of antimicrobial a.i. sold per tonne of live weight of animals slaughtered for food | 0.08 | 0.08 | 0.07 | 0.06 | 0.06 | 0.06 |

* Data are ratioed only against total therapeutic antimicrobials as no antimicrobial growth promoters were sold for use, see Table 5.



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ANTIMICROBIAL SALES AND OTHER FOOD ANIMAL COMMODITIES

Cows' milk production in the UK annually, expressed in millions of litres, is detailed in Table 17. The Defra Statistics (Commodities and Food) Division provided the data for milk production. These data have been compared to the quantities of intramammary products sold over the same period for use in lactating cows. Over the reporting period the quantity of milk produced for each tonne of intramammary product sold for use in lactating cows has fluctuated. Using the same data we can estimate that around 0.1mg of antimicrobial was sold per litre of milk produced.

Table 17: Litres of milk produced per kilogram of antimicrobial lactating cow intramammary product (kilograms active ingredient) sold 2003-2008

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|--------|--------|--------|--------|--------|--------|
| Million litres milk produced | 14,583 | 14,134 | 14,059 | 13,914 | 13,632 | 13,332 |
| Kilograms a.i. lactating intramammary sold | 2,145 | 1,886 | 1,375 | 1,266 | 1,383 | 1,775 |
| Million litres milk produced per tonne a.i. lactating intramammary sold | 6,799 | 7,494 | 10,225 | 11,991 | 9,857 | 7,511 |
| Kilograms a.i. lactating intramammary sold per million litre of milk produced | 0.15 | 0.13 | 0.10 | 0.09 | 0.10 | 0.13 |

In addition not all of the approximately 13 billion litres of milk produced annually in the UK (excluding suckled milk) are sold for human consumption. It is estimated that approximately 183 million litres of milk produced are fed back to calves and other animals (e.g. pigs) or are treated on farm as waste in 2008. If milk is produced over the allowed EU quotas it may also be destroyed.



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HOW CAN WE IMPROVE THIS REPORT?

We would welcome any comments that readers have on this report.

We will continue to strive to improve this report within the limitations of the data supplied.

We are looking to improve our understanding of the effects of changes in the patterns of sales of antimicrobial products through comparing our figures with other validated information held by Defra and other Government Departments, and in other countries. At the time of publishing this report, a number of Government Agencies including the VMD, Defra, FSA, HPA and DH were drafting the second Overview of Antimicrobial Usage and Bacterial Resistance in Selected Human and Animal Pathogens in the UK. The aim is to publish the Overview Report during Winter 2009/10. This second Overview report will be available on the VMD website under the 'publications' and 'antibiotic related' tabs along side the original report covering data for 2004.

We are keen to maximise the value of the published figures to stakeholders. We would welcome any comments that you might have about the contents of this report, including the categories under which information is reported, and on our proposals for improvements.

We would also welcome any information or interpretations that you may have on the patterns and trends of sales of antimicrobials noted in this report. These should be sent to Dr Kay Goodyear at:

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**VETERINARY MEDICINES DIRECTORATE
October 2009**



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ANNEX 1: GLOSSARY OF TERMS

| | |
|---------------------------------|--|
| a.i. | Active Ingredient; the part of an antimicrobial medicine that acts against the bacterial infection. |
| Aminoglycosides | A closely related group of bactericidal antibiotics derived from bacteria of the order Actinomycetales. Polycationic compounds that contain an aminocyclitol with cyclic amino-sugars attached by glycoside linkages. Sulphate salts are generally used. They have broadly similar toxicological features. |
| Antibiotic | A substance produced by or derived from a micro-organism, which selectively destroys or inhibits the growth of other micro-organisms. |
| Antifungal | Products that are destructive to or suppress the reproduction or growth of fungi. |
| Antimicrobial | A compound which, at low concentrations, exerts an action against micro-organisms and exhibits selective toxicity towards them. The term includes any substance of natural, synthetic or semi-synthetic origin that is used to kill, or inhibit the growth of, micro-organisms (bacteria, fungi, protozoa and viruses). Antimicrobials include antibiotics, disinfectants, preservatives and other substances. |
| Antimicrobial Resistance | The ability of a micro-organism to grow or survive in the presence of an antimicrobial that is usually sufficient to inhibit or kill micro-organisms of the same species. |
| Antiprotozoal | A drug primarily used in the treatment and/or prevention of parasitic protozoal infections. |
| β-Lactam | Semi-synthetic antibiotics derived from penicillin G or cephalosporin C, natural antibiotics produced by the mould <i>Cephalosporium acremonium</i> . Bactericidal products that act by inhibiting synthesis of the bacterial cell wall. |
| Coccidiostat | Product used for the control of coccidiosis, a protozoal infection causing diarrhoea and dysentery. |
| Defra | Department for Environment, Food and Rural Affairs. |



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| | |
|-----------------------------------|--|
| Fluoroquinolone | A sub-group of the quinolone compounds, having the addition of a fluorine atom and the 7-piperazinyl group. Broad-spectrum antibacterials with properties more suited to the treatment of systemic infections. |
| Food Animals | Animals produced for food including: cattle, sheep, pigs, poultry, salmon, trout and bees. |
| Growth Promoter | Substances, which, when given in animal feed, increase feed conversion efficiency or result in better daily live weight gain, or both. |
| Injectable Product | A therapeutic product which is administered to animals via injection. |
| Intramammary Product | A product which is administered into the udder. |
| Ionophore | A small hydrophobic molecule that dissolves in lipid bilayer membranes and increases permeability to inorganic ions. |
| Macrolide | A large group of antibiotics mainly derived from <i>Streptomyces</i> spp. Weak bases that are only slightly soluble in water. They have low toxicity and similar antimicrobial activity with cross-resistance between individual members of the group. Thought to act by interfering with bacterial protein synthesis. |
| Medicated Feedingstuff | Feedingstuffs that contain a veterinary medicine and that are intended for feeding to animals without further processing. |
| Non-Food Animals | Animals not reared for food. These are mainly companion animals including, dogs, cats, horses, small mammals, rabbits and birds. |
| Non Ionophore Coccidiostat | All coccidiostats with alternative modes of action to those shown by ionophores. |
| PDNS | Porcine Dermatitis and Nephropathy Syndrome, a disease affecting pigs. |
| PMWS | Post-weaning Multi-systemic Wasting Syndrome, a disease affecting pigs. |
| Special Import Certificate | A certificate issued by the VMD on behalf of the Secretary of State to permit veterinary surgeons to legally import veterinary medicinal products with current EU authorisations into the UK to treat animals under the 'cascade'. |



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| | |
|--------------------------------------|---|
| Special Treatment Certificate | A certificate issued by the VMD on behalf of the Secretary of State to permit veterinary surgeons to legally import other products/substances, where the health situation demands and where there is no EU authorised treatment available. |
| Sulphonamide | A group of bacteriostatic compounds that interfere with folic acid synthesis of susceptible organisms. They all have similar antimicrobial activity but different pharmacokinetic properties. |
| Tetracycline | A group of antibiotics derived from <i>Streptomyces</i> spp. They are usually bacteriostatic at concentrations achieved in the body and act by interfering with protein synthesis in susceptible organisms. All have a broad spectrum of activity. |
| Therapeutic Product | A product which treats or prevents disease. |
| Trimethoprim | Compounds with a similar action to sulphonamides, acting by interfering with folic acid synthesis, but at a different stage in the metabolic pathway. Display a similar spectrum of activity to, and are often used in combination with, sulphonamides. |
| VMD | Veterinary Medicines Directorate, an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). |
| Water/Oral Product | A therapeutic product that is administered to animals orally. Includes tablets, boluses, capsules, dissolvable powders and sachets, solutions, etc. |
| Zotechnical Feed Additive | A high technology feed additive used routinely in low doses to affect favourably the performance of animals in good health. Includes non-antimicrobial growth promoters, coccidiostats and histomonostats. |



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ANNEX 2: CONTRIBUTORS AND PARTICIPANTS

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UK

Contributing Pharmaceutical Companies and Other Marketing Authorisation Holders

Alpharma Inc
Animal Care Ltd
AniMedica
Bayer Plc
Boehringer Ingelheim Ltd
CEVA Animal Health Ltd
Chanelle Animal Health Ltd
Chemo Iberica, SA
Cross Vetpharm Group Ltd
Cyton Biosciences Ltd
Dechra
ECO Animal Health Ltd
Eli Lilly
European Veterinary Supplies Ltd
Eurovet Animal Health
Fort Dodge Animal Health Ltd
Forum Products Ltd
Globalmed Ltd
Harkers Ltd
Hipra
Huvepharma
Intervet (UK) Ltd
Janssen Cilag Ltd
Krka Dd
Lavet Pharmaceuticals Ltd
Merial Animal Health Ltd
Minster Veterinary Practice
Norbrook Laboratories Ltd
Novartis Animal Health Ltd



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Novartis Animal Health Vaccines Ltd
Oropharma
Pfizer Ltd
PHARMAQ Ltd
Phibro Animal Health SA
Quvera Ltd
Schering Plough Animal Health
Sogeval
Vétoquinol UK Ltd
Virbac S.A

Statistical Contributors

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